

**Notice of Allowability****Application No.**

10/551,789

**Examiner**

ERIC S. OLSON

**Applicant(s)**

CLANDININ ET AL.

**Art Unit**

1623

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's amendment submitted March 15, 2010.
2. ☒ The allowed claim(s) is/are 17,21-23 and 25.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 3/8/2010
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3/7/2010
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_.

/Eric S Olson/  
Examiner, Art Unit 1623

**Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Gould on May 7, 2010.

Claims 3, 6, 7, 11, 13, and 28-32 are cancelled.

### **Detailed Action**

This office action is a response to applicant's communication submitted March 15, 2010 wherein claims 13 and 25, and 28 are amended. This application is a national stage application of PCT/CA04/00375, filed March 12, 2004, which claims priority to US application 10/404095, now US patent 6998392, filed April 2, 2003.

Claims 17, 21-23, and 25 are pending in this application.

Claims 17, 21-23, and 25 as amended are examined on the merits herein.

### **Reasons for Allowance**

Applicant's amendment, submitted March 15, 2010, and the enclosed examiner's amendment, with respect to the rejection of instant claims 3, 6, 7, 11, 13, 17, 21-23, 25, and 28-32 under 35 USC 103(a) for being obvious over Ettinger in view of Pan et al. in view of Merck, have been fully considered and found to be persuasive to remove the rejection as the base claim 25 has been amended to require that the subject actually have elevated cholesterol, and claims 3, 6, 7, 11, 13, and 28-32 are cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 15, 2010, with respect to the rejection of instant claims 17, 21-23, and 25 under 35 USC 103(a) for being obvious over Berger et al., has been fully considered and found to be persuasive to remove the rejection as the base claim 25 has been amended to require that the subject actually have elevated cholesterol. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 15, 2010, with respect to the rejection of instant claims 17, 21-23, and 25 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 1-5 of US patent 6998392, has been fully considered and found to be persuasive to remove the rejection as the base claim 25 has been amended to require that the subject actually have elevated cholesterol. Therefore the rejection is withdrawn.

Currently claims 17, 21-23, and 25 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted March 15, 2010, and the enclosed examiner's amendment, are seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claimed invention is seen to be adequately described and enabled by the specification as originally filed. Therefore the claims meet the requirements of 35 USC 112.

Furthermore the claimed invention is seen to be novel and non-obvious over the prior art. Although the prior art discloses compositions containing gangliosides wherein over 50% of the gangliosides are ganglioside GD3, for example human colostrum gangliosides as described by Pan et al., the prior art does not disclose administering these specific ganglioside compositions to a subject having elevated plasma cholesterol. One of ordinary skill in the art would not have been motivated by any

additional prior art references to administer these compositions (i.e. human colostrum gangliosides) to such a subject. Therefore the claims meet the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment submitted March 15, 2010, and the enclosed examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
5/10/2010